

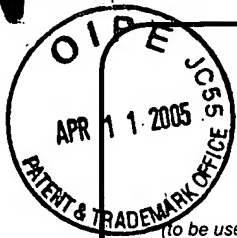
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PTO/SB/21 (09-04)

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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number		10/780,439	
Filing Date		02-17-2004	
First Named Inventor		Philip D. Cook, et al.	
Art Unit		1637	
Examiner Name		Not yet assigned	
Total Number of Pages in This Submission	42	Attorney Docket Number	ISIC0006-102 (ISIS-4380US.C1)

## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): PTO-1449 Modified (38 pp.) Information Disclosure Statement (4 pp.)
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Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

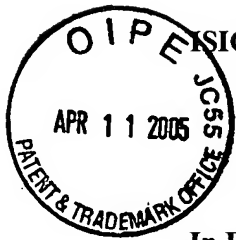
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ISIC0006-102 (ISIS-4380US.C1)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Philip D. Cook, et al.

Serial No.: 10/780,439

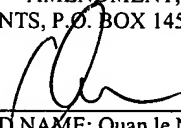
Group Art Unit: 1637

Filing Date: 02/17/2004

Examiner: Not yet assigned

**For: Compositions And Methods For Enhanced Biostability And Altered Biodistribution Of Oligonucleotides In Mammals**

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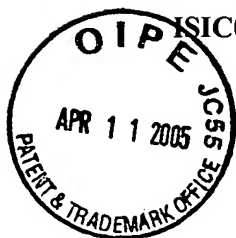
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**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.



ISIC0006-102 (ISIS-4380US.C1)

PATENT

**This Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:

☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);

**or**

☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or

☐ No fee is owed by the applicant(s).

- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with the ☐ first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.

- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).

- ☐ Copies of references (AA-AP) listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed.

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of references, and the likelihood that these reference are available to the Examiner, copies are not enclosed herewith.

- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) @@ for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.



ISIC0006-102 (ISIS-4380US.C1)

PATENT

- ☒ Copies of references listed on the attached PTO Form SB/08A, formerly known as PTO Form 1449, were previously cited by or submitted to the U.S. Patent and Trademark Office in parent application Serial No. 08/928,823 filed on 12 September 1997.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 C.F.R. § 1.704(d)**

- ☐ The undersigned attorney hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and the communication was not received by any individual designated in § 1.56(c) more than 30 days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.



ISIC0006-102 (ISIS-4380US.C1)

PATENT



No fee or Statement is required under 37 C.F.R. § 1.97(b).

Respectfully submitted,

Quan le Nguyen  
Registration No. 46,957

Dated: Apr 11/05

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<b>Form PTO-1449 Modified</b>		Docket No. ISIC0006-102 (ISIS-4380US.C1)	Serial No. 10/780,439
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)		Applicant <b>Philip D. Cook et al.</b>	
U.S. Department of Commerce Patent and Trademark Office		Filing Date 02/17/2004	Group 1637
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	AA	Asseline, U. et al., "Solid-Phase Preparation of 5'-3'-Heterobifunctional Oligodeoxyribonucleotides Using Modified Solid Supports", <i>Tetrahedron</i> 1992, 48, 1233-1254	
	AB	Asseline, U. et al., "Nucleic acid-binding molecules with high affinity and base sequence specificity: Intercalating agents covalently linked to oligodeoxynucleotides", <i>Proc. Natl. Acad. Sci. USA</i> 1984, 81, 3297-3301	
	AC	Atherton, E. et al., <i>The Peptides</i> , Gross and Meienhofer, Eds, Academic Press; New York, Vol. 9:1-38, 1983	
	AD	Baker, B.F., "Decapitation of a 5'-Capped Oligoribonucleotide by o-Phenanthroline: CU(II)", <i>J. Am. Chem. Soc.</i> 1993, 115, 3378-3379	
	AE	Beaucage, S. et al., "Advances in the Synthesis of Oligonucleotides by the Phosphoramidite Approach", <i>Tetrahedron</i> 1992, 48, 2223-2311	
	AF	Bennett, C.F. et al., "Cationic Lipids Enhance Cellular Uptake and Activity of Phosphorothioate Antisense Oligonucleotides", <i>Molecular Pharmacology</i> 1991, 41, 1023-1033	
	AG	Betebenner, D.A., et al., "Hepatobiliary Delivery of Polyaminopolycarboxylate Chelates: Synthesis and Characterization of a Cholic Acid Conjugate of EDTA and Biodistribution and Imaging Studies with Its Indium-111 Chelate", <i>Bioconjugate Chem.</i> 1991, 2, 117-123	
	AH	Bischoff, R. et al., "Introduction of 5'-Terminal Functional Groups into Synthetic Oligonucleotides for Selective Immobilization", <i>Analy. Biochem.</i> 1987, 164, 336-344	
	AI	Blackburn, G. et al., "Studies in Phosphorylation. Part XXIX. The Synthesis of Dialkyl Phosphates from Monoalkyl Phosphonates: Direct Oxidative Esterification", <i>J. Chem. Soc.</i> 1966, 239-245	
	AJ	Chiang, M.-Y. et al., "Antisense Oligonucleotides Inhibit-Intercellular Adhesion Molecule 1 Expression by Two Distinct Mechanisms", <i>J. of Biol. Chem.</i> 1991, 266, 18162-18171	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. ISIC0006-102 (ISIS-4380US.C1)	Serial No. 10/780,439
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		Filing Date 02/17/2004	Group 1637
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>AK</b>	Chollet, A., "Selective Attachment of Oligonucleotides to Interleukin-1 beta and Targeted Delivery to Cells", <i>Nucleosides &amp; Nucleotides</i> 1990, 9, 957-966.	
	<b>AL</b>	Cohen, J. in <i>Oligonucleotides: Antisense Inhibitors of Gene Expression</i> , CRC Press, Inc., Boca Raton, FL, 1989	
	<b>AM</b>	Corey, D. et al., "Sequence-Selective Hydrolysis of Duplex DNA by an Oligonucleotide-Directed Nuclease", <i>J. Am. Chem. Soc.</i> 1989, 111, 8523-8525.	
	<b>AN</b>	Corey, D. et al., "Generation of a Hybrid Sequence-Specific Single-Stranded Deoxyribonuclease", <i>Science</i> 1987, 238, 1401-1403.	
	<b>AO</b>	Damha, M. et al., "An Improved Procedure for Derivatization of Controlled-Pore Glass Beads for Solid-Phase Oligonucleotide Synthesis", <i>Nuc. Acids Res.</i> 1990, 18, 3813-3821.	
	<b>AP</b>	Delgado, C. et al., "The Uses and Properties of PEG-Linked Proteins", <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 1992, 9, 249-304.	
	<b>AQ</b>	Dingwall, C., et al., "Protein Import Into the Cell Nucleus", <i>Ann. Rev. Cell Biol.</i> 1986, 2, 367-90.	
	<b>AR</b>	DiZio, J. et al., "Progestin-Thenium Complexes: Metal-Labeled Steroids with High Receptor Binding Affinity, Potential Receptor-Directed Agents for Diagnostic of Therapy", <i>Bioconjugate Chem.</i> 1991, 2, 353-366.	
	<b>AS</b>	Dreyer, G. et al., "Sequence-Specific Cleavage of Single-Stranded DNA: Oligodeoxynucleotide-EDTA.Fe(II)", <i>PNAS USA</i> 1985, 82, 968-972.	
	<b>AT</b>	Egholm, M. et al., "Peptide Nucleic Acids (PNA). Oligonucleotide Analogues with an Achiral Peptide Backbone", <i>J. Am. Chem. Soc.</i> 1992, 114, 1895-1897.	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>AU</b>	Ferentz, A.E. and Verdine, G.L., "Disulfide Cross-Linked Oligonucleotides", <i>J. Am. Chem. Soc.</i> 1991, 113, 4000-4003.	
	<b>AV</b>	Fidanza, J. et al., "Site-Specific Labeling of DNA Sequences Containing Phosphorothioate Diesters", <i>J. Am. Chem. Soc.</i> 1992, 114, 5509-5517.	
	<b>AW</b>	Fidanza, J. et al., "Use of a Thiol Tether for the Site-Specific Attachment of Reporter Groups of DNA", <i>J. Org. Chem.</i> 1992, 57, 2340-2346.	
	<b>AX</b>	Froehler, B. et al., "Synthesis of DNA via Deoxynucleoside H-Phosphonate Intermediates", <i>Nucleic Acids Research</i> 1986, 14, 5399-5407.	
	<b>AY</b>	Gaur, R. et al., "A Simple Method for the Introduction of Thiol Group at 5'-Termini of Oligodeoxynucleotides", <i>Nuc. Acids Res.</i> 1989, 17, 4404.	
	<b>AZ</b>	Greene et al., <i>Protective Groups in Organic Synthesis</i> , 2nd edition, New York, John Wiley & Sons, pp. 178-223, 1991	
	<b>BA</b>	Greenfield, L. et al., "Thiol-Containing Cross-Linking Agent with Enhanced Stearic Hindrance", <i>Bioconjugate Chem.</i> 1990, 1, 400-410.	
	<b>BB</b>	Guerra, F.I. et al., "Synthetic 7-Glucosyl Phospholipid as a Drug Transport System", <i>Tetrahedron Letters</i> 1987, 28, 3581-3584.	
	<b>BC</b>	Haralambidis J., et al., "Preparation of Base-modified Nucleosides Suitable for Non-Radioactive Label Attachment and Their Incorporation Into Synthetic Oligodeoxyribonucleotides", <i>Nucleic Acids Research</i> 1987, 15, 4857-4876.	
	<b>BD</b>	Haralambidis, J. et al., "The Solid Phase Synthesis of Oligonucleotides containing a 3'-Peptide Moiety", <i>Tetrahedron Letters</i> 1987, 28, 5199-5202.	
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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>BE</b>	Harris, C. et al., "New Strategy for the Synthesis of Oligodeoxynucleotides Bearing Adducts at Exocyclic Amino Sites of Purine Nucleosides", <i>J. Am. Chem. Soc.</i> 1991, 113, 4328-4329.	
	<b>BF</b>	Iyer, R. et al., "3H-1, 2-Benzodithiole-3-one, 1,1,-Dioxide as an Improved Sulfurizing Reagent in the Solid-Phase Synthesis of Oligodeoxyribonucleoside Phosphorothioates", <i>J. Am. Chem. Soc.</i> 1990, 112, 1253-1254.	
	<b>BG</b>	Jablonski, E. et al., "Preparation of Oligodeoxynucleotide-Alkaline Phosphatase Conjugates and Their Use as Hybridization Probes", <i>Nucleic Acid Research</i> 1986, 14, 6115-28.	
	<b>BH</b>	Juby, C.D., et al., "Facile Preparation of 3'Oligonucleotide-Peptide Conjugates", <i>Tetrahedron Letters</i> 1991, 32, 879-882.	
	<b>BI</b>	Krieg, A.M., et al., "Uptake of Oligodeoxyribonucleotides by Lymphoid Cells Is Heterogeneous and Inducible", <i>Antisense Research and Development</i> 1991 1, 161-171.	
	<b>BJ</b>	Lemaitre, M. et al., "Specific Antiviral Activity of a Poly(L-lysine)-Conjugated Oligodeoxyribonucleotide Sequence Complementary to Vesicular Stomatitis Virus N Protein mRNA Initiation Site", <i>PNAS USA</i> 1987, 84, 648-652.	
	<b>BK</b>	Leonetti, J.P. et al, "Biological Activity of Oligonucleotide-Poly(L-lysine) Conjugates: Mechanism of Cell Uptake", <i>Bioconjugate Chem.</i> 1990, 1, 149-153.	
	<b>BL</b>	Letsinger, R.L., et al., "Cholesteryl-Conjugated Oligonucleotides: Synthesis, Properties, and Activity as Inhibitors of Replication of Human Immunodeficiency Virus in Cell Culture", <i>Proc. Natl. Acad. Sci. USA</i> 1989, 86, 6553-6556.	
	<b>BM</b>	MacMillan, A. et al, "Synthesis of Functionally Tethered Oligodeoxynucleotides by the Convertible Nucleoside Approach", <i>J. Org. Chem.</i> 1990, 55, 5931-5933.	
	<b>BN</b>	Manoharan, M. et al., "Novel Functionalization of the Sugar Moiety of Nucleic Acids For Multiple Labeling in the Minor Groove", <i>Tetra.Ltrs.</i> 32:7171-7174 (1991).	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

<b>Form PTO-1449 Modified</b>		<b>Docket No.</b> ISIC0006-102 (ISIS-4380US.C1)	<b>Serial No.</b> 10/780,439
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)		<b>Applicant</b> Philip D. Cook et al.	
U.S. Department of Commerce Patent and Trademark Office		<b>Filing Date</b> 02/17/2004	<b>Group</b> 1637
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>BO</b>	Meyer, R. et al., "Efficient, Specific Cross-Linking and Cleavage of DNA by Stable, Synthetic Complementary Oligodeoxynucleotides", <i>J. Am. Chem. Soc.</i> 1989, 111, 8517-8519.	
	<b>BP</b>	Miller, P.S. et al., "A New Approach to Chemotherapy Based on Molecular Biology and Nucleic Acid Chemistry: Matagen: Masking Tape for Gene Expression", <i>Anti-Cancer Drug Design</i> 1987, 2, 117-128.	
	<b>BQ</b>	Mirabelli, C.K. et al., "In vitro and in vivo pharmacologic activities of antisense oligonucleotides", <i>Anti-Cancer Drug Design</i> 1991, 6, 647-661.	
	<b>BR</b>	Mori, K. et al., "Synthesis and Properties of Novel 5'-Linked Oligos", <i>Nucleosides &amp; Nucleotides</i> 1989, 8, 649-657.	
	<b>BS</b>	Nelson, P. et al., "Bifunctional Oligonucleotide Probes Synthesized Using a Novel CPG Support Are Able to Detect Single Base Pair Mutants", <i>Nuc. Acids Res.</i> 1989, 17, 7187-7194.	
	<b>BT</b>	Ouchi, T. et al., "Synthesis and Antitumor Activity of Poly(Ethylene Glycol)s Linked to 5-Fluorouracil Via a Urethan or Urea Bond", <i>Drug Design and Discovery</i> 1992, 9, 93-105.	
	<b>BU</b>	Pidgeon, C. et al., "Synthesis and Liposome Encapsulation of Antisense Oligonucleotide-Intercalator Conjugates", <i>Annals New York Academy of Sciences</i> pp. 593-596.	
	<b>BV</b>	Ramirez, F. et al., "Nucleotidophospholipids: Oligonucleotide Derivatives with Membrane-Recognition Groups", <i>J. Am. Chem. Soc.</i> 1982, 104, 5483-5486.	
	<b>BW</b>	Ravasio, N. et al., "Selective Hydrogenations Promoted by Copper Catalysts. 1. Chemoselectivity, Regioselectivity, and Stereoselectivity in the Hydrogenation of 3-Substituted Steroids", <i>J. Org. Chem.</i> 1991, 56, 4329-4333.	
	<b>BX</b>	Shea, R. et al., "Synthesis, Hybridization Properties and Antiviral Activity of Lipid-Oligodeoxynucleotide Conjugates", <i>Nuc. Acids Res.</i> 1990, 18, 3777-3783.	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. ISIC0006-102 (ISIS-4380US C1)	Serial No. 10/780,439
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		Filing Date 02/17/2004	Group 1637
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>BY</b>	Sigman, D.S., "Chemical Nucleases", <i>Biochemistry</i> 1990, 29, 9097-9105.	
	<b>BZ</b>	Sinha, N.D. et al., "The Preparation and Application of Functionalized Synthetic Oligonucleotides: III. Use of H-Phosphonate Derivatives of Protected Amino-Hexanol and Mercapto-Propanol or -Hexanol", <i>Nucleic Acids Res.</i> 1988, 16, 2659-2669.	
	<b>CA</b>	Sluka, J. et al., "Reagents and Methods for the Solid-Phase Synthesis of Protein-EDTA for Use in Affinity Cleaving", <i>J. Am. Chem. Soc.</i> 1990, 112, 6369-6374.	
	<b>CB</b>	Smith-Jones, P. et al., "Antibody Labeling with Copper-67 Using the Bifunctional Macrocycle 4-((1,4,8,11-Tetraazacyclotetradec-1-yl)methyl)Benzoic Acid", <i>Bioconjugate Chem.</i> 1991, 2, 415-421.	
	<b>CC</b>	Solomons, T.W. et al., <i>Organic Chemistry</i> , John Wiley & Sons, New York, pp. 818-819, 1980.	
	<b>CD</b>	Sproat, B. et al., "The Synthesis of Protected 5'-Mercapto-2',5'-Dideoxyribonucleoside-3'-O-Phosphoramidites; Uses of 5'-Mercapto-Oligodeoxyribonucleotides", <i>Nucleic Acids Res.</i> 1987, 15, 4837-4848.	
	<b>CE</b>	Stein, C. et al., "Antisense Oligonucleotides as Therapeutic Agents--Is the Bullet Really Magical?" <i>Science</i> 1993, 261, 1004-1012.	
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	<b>CG</b>	Tseng, B. et al., "Antisense Oligonucleotide Technology in the Development of Cancer Therapeutics", <i>Cancer Gene Therapy</i> 1994, 1(1), 65-71.	
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